

Translation

PATENT COOPERATION TREATY

PCT/FR2003/001407



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference OB/ACH/42177	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/FR2003/001407	International filing date (day/month/year) 06 mai 2003 (06.05.2003)	Priority date (day/month/year) 07 mai 2002 (07.05.2002)
International Patent Classification (IPC) or national classification and IPC A61M 5/00		
Applicant BECTON DICKINSON FRANCE		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 24 novembre 2003 (24.11.2003)	Date of completion of this report 16 February 2004 (16.02.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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International application No.

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I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages _____ 1-10 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages _____ 1-19 _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the drawings:
 pages _____ 1/2-2/2 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-19	YES
	Claims		NO
Inventive step (IS)	Claims	1-19	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-19	YES
	Claims		NO

2. Citations and explanations

1. Reference is made to the following documents:

- D1: EP-A-0 266 688 (BASF AG) 11 May 1988
(1988-05-11)
- D2: US-A-3 503 497 (ADILETTA JOSEPH G ET AL)
31 March 1970 (1970-03-31)
- D3: US-A-5 868 244 (IVANOV KONSTANTIN ET AL)
9 February 1999 (1999-02-09)
- D4: EP-A-0 307 173 (AHLSTROEM OY) 15 March 1989
(1989-03-15)
- D5: EP-A-0 846 445 (HUYNEN MARC; HUYNEN STEPHANE
(BE)) 10 June 1998 (1998-06-10)
- D6: DE 15 86 778 B (LINDER FRITZ DR) 7 October 1971
(1971-10-07)
- D7: US-A-3 302 859 (PERRY RAY P) 7 February 1967
(1967-02-07)

2. The closest prior art is represented by D1 (EP 0266688), which discloses packaging designed to be used for transporting sterile objects or objects which are to be sterilized, the packaging comprising a box (1) for receiving the sterile objects or objects to be sterilized and a cover sheet (4) secured to the box so as to seal it. The cover sheet

is made from a material which is impervious to a decontamination gas and has at least one window (2) which is closed by a part (3) made of selectively impervious material.

The difference between the application and D1 is a flexible part which is made of a material that is impervious to a decontamination gas and is secured to the cover sheet. Therefore the subject matter of claim 1 is novel (PCT Article 33(2)).

3. The problem addressed by the present invention can thus be considered that of producing packaging which can be decontaminated without the objects inside the packaging coming into contact with the decontaminating gas. The prior art does not mention this problem or its solution, and even if it is considered that the use of flexible parts as valves is already known (from D7, for example), it is not obvious to apply this principle to the context of sterilization followed by a decontamination phase, as proposed in the application.

Therefore the subject matter of claim 1 involves an inventive step (PCT Article 33(3)).

4. Similarly, the production method according to claim 14, the use according to claims 17 and 18, and the sterilizing method according to claim 19 are novel and involve an inventive step.
5. Claims 2 to 13 are dependent on claim 1 and claims 15 and 16 are dependent on claim 14; thus they likewise meet the PCT novelty and inventive step requirements.

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6. Contrary to the requirements of PCT Rule 5.1(a)(ii), the description does not cite D1 or the relevant prior art contained therein.